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Regulatory Fundamentals

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Preface

The Canadian Nuclear Safety Commission (CNSC) is the federal organization responsible for regulating the use of nuclear energy and materials in Canada. It regulates to protect health, safety, security and the environment, and to implement Canada's international commitments on the peaceful use of nuclear energy. The CNSC also disseminates objective scientific, technical, and regulatory information to the public.

Regulatory document REGDOC-3.5.3, *Regulatory Fundamentals*, outlines the CNSC's regulatory philosophy and approach to applying the Nuclear Safety and Control Act. It provides information for licensees, applicants and the public, and contains neither guidance nor requirements. It replaces P-299, *Regulatory Fundamentals* (2005) and INFO-0795, *Licensing Basis - Objective and Definitions* (2010).

This regulatory document is part of the CNSC's processes and practices series of regulatory documents, which also covers information on licensing processes, compliance, and enforcement. The full list of regulatory documents is included at the end of this document, and can also be found on the CNSC's website.

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Regulatory Fundamentals

1. Introduction

1.1 Purpose

This regulatory document is intended for information only and does not contain any requirements for CNSC licensees. It describes the CNSC's regulatory approach and philosophy, and outlines how the CNSC applies the NSCA and regulations made under the authority of the NSCA in its regulatory oversight. The information in this regulatory document will be of interest to anyone seeking to learn more about the CNSC and how it regulates nuclear activity in Canada.

1.2 Scope

This document describes the CNSC's regulatory activities.

2. About the CNSC

Regulation is a key instrument used by government to enable economic activity and to protect health, safety, security and the environment in Canada. The Government of Canada has determined that the use of nuclear substances and nuclear energy offers benefits, and that the associated risks must not be at an unreasonable level. These two facts drive the need for Canadian legislation and a regulatory body to oversee nuclear activities in Canada.

The *Nuclear Safety and Control Act* (NSCA) came into force on May 31, 2000. It establishes the Canadian Nuclear Safety Commission (CNSC), its objects, and the framework under which it can effectively and independently meet those objects. The CNSC was established in 2000 under the NSCA and reports to Parliament through the Minister of Natural Resources. The CNSC replaced the former Atomic Energy Control Board, which was founded in 1946.

The CNSC is the sole authority in Canada to regulate the development, production and use of nuclear energy, and the production, possession and use of nuclear substances, prescribed equipment and prescribed information in order to prevent unreasonable risk. The CNSC's mandate also requires it to disseminate objective scientific, technical and regulatory information to the public.

Parliament has also given the CNSC the authority to conduct environmental assessments under the *Canadian Environmental Assessment Act, 2012*.

The CNSC has also been delegated authority to implement Canada's agreement with the International Atomic Energy Agency on nuclear safeguards verification. For more information, see the *Agreement Between the Government of Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons* [1] and the *Protocol Additional to the Agreement between Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons* [2].

2.1 The Commission

The Commission[1] is an independent, quasi-judicial tribunal and a court of record, with the powers, rights, and privileges necessary to carry out its duties and enforce its orders. It has a central role in CNSC operations, and operates at arm's length from the government with no ties to the nuclear industry.

The Commission has up to seven permanent members, who are appointed by the Governor in Council for terms of up to five years. One member is designated as President of the Commission and Chief Executive Officer of the CNSC.

Subject to the approval of the Governor in Council[2], the Commission may make and amend regulations as it deems necessary for attaining the objects of the NSCA. The Commission is also empowered to grant licences to conduct nuclear activities. Commission decisions are science- and safety-based; they may not be overturned by the Government of Canada, and they are reviewable only by the Federal Court of Canada. These measures help ensure the independence of the Commission.

The Governor in Council may issue directives to the CNSC. Any such directive may only be of general application on broad policy matters with respect to the objects of the Commission, and not in respect of a particular case before the Commission.

To maintain its adjudicative distance from CNSC staff, the Commission communicates with staff only through the Commission Secretariat and through formal proceedings. This separation serves to maintain the Commission's independence.

2.2 CNSC staff

The Commission employs the staff it considers necessary for the purposes of the NSCA.

The CNSC has highly skilled scientific, technical, professional and administrative personnel who carry out the work necessary to fulfill the Commission's mandate. CNSC staff perform several functions such as:

- conducting expert research and analysis
- verifying licensee compliance with regulatory requirements
- conducting activities to enforce licensee compliance, when necessary
- preparing material, known as Commission member documents (CMDs), for the Commission and appearing before the Commission at proceedings to answer questions
- carrying out a wide range of internal activities that enable the success of the CNSC's core operational work

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[1] In this document, the term "Commission" refers to the appointed members forming the Commission.
[2] In Canada, the Governor in Council is the Governor General acting on the advice of Cabinet.

The Commission may also enter into contracts for services to receive advice and assistance in the exercise or performance of any of its powers, duties or functions under the NSCA.

2.3 What the CNSC regulates

The CNSC regulates the conduct of activities related to the use, production and distribution of nuclear energy and substances as defined by section 26 of the NSCA. This includes activities related to:

- uranium mines and mills
- uranium fuel fabrication and processing
- nuclear power plants
- nuclear substance processing
- industrial and medical applications
- nuclear research and educational activities
- transportation of nuclear substances
- nuclear security and safeguards
- import and export activities
- waste management facilities

3. The CNSC's Regulatory Framework

The CNSC's regulatory framework (see figure 1) consists of the *Nuclear Safety and Control Act* (NSCA) and other laws passed by Parliament that govern the regulation of Canada's nuclear industry, as well as regulations, licences and documents that the CNSC uses to regulate the industry.

Figure 1: Key elements of the CNSC's regulatory framework

The regulatory framework also includes guidance, which is used to inform the applicant or licensees on how to meet requirements, elaborate further on requirements, or provide best practices. While the CNSC sets requirements and provides guidance on how to meet requirements, an applicant or licensee may put forward a case to demonstrate that the intent of a requirement is addressed by other means. Such a case must be demonstrated with supportable evidence. CNSC staff consider guidance when evaluating the adequacy of any case submitted. This does not mean that the requirement is waived; rather, it is an indication that the regulatory framework provides flexibility for licensees to propose alternative means of achieving the intent of the requirement. The Commission is always the final authority as to whether the requirement has been met.

CNSC requirements and guidance take into account international regulatory best practices and modern codes and standards, and align with the International Atomic Energy Agency's Safety Fundamentals and Safety Requirements. The CNSC cooperates with other organizations and jurisdictions to foster the development and application of a consistent, effective regulatory framework in Canada and for international nuclear regulators. The CNSC welcomes stakeholder feedback on its regulatory framework at any time.

Further information on the CNSC's regulatory framework can be found on the CNSC's Regulatory framework overview Web page.

3.1 The *Nuclear Safety and Control Act*

The NSCA establishes the CNSC's mandate to regulate the development, production, and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information in Canada.

The mandate of the CNSC is informed by the objects of the Commission, set out in section 9 of the NSCA, which are:

> (a) to regulate the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information in order to
>
> > (i) prevent unreasonable risk, to the environment and to the health and safety of persons, associated with that development, production, possession or use,
> >
> > (ii) prevent unreasonable risk to national security associated with that development, production, possession or use, and
> >
> > (iii) achieve conformity with measures of control and international obligations to which Canada has agreed; and
>
> (b) to disseminate objective scientific, technical and regulatory information to the public concerning the activities of the Commission and the effects, on the environment and on the health and safety of persons, of the development, production, possession and use referred to in paragraph (a).

When making licensing decisions, the Commission is guided by section 24, paragraph 4 of the NSCA, which states:

> No licence shall be issued, renewed, amended or replaced — and no authorization to transfer one given — unless, in the opinion of the Commission, the applicant or, in the case of an application for an authorization to transfer the licence, the transferee
>
> (a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and
>
> (b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

3.2 Regulations made under the *Nuclear Safety and Control Act*

The regulations made under the NSCA provide further legislative authority with respect to topic-specific considerations, using a combination of prescriptive and performance-based approaches. Prescriptive approaches tell licensees exactly what they need to do to meet requirements, whereas performance-based approaches set specific performance measures that licensees must meet with respect to particular aspects of their licensed activities.

There are 13 regulations under the NSCA, including the *General Nuclear Safety and Control Regulations* and the *Radiation Protection Regulations*. Regulations under the NSCA describe the general application of requirements for nuclear activity in Canada, and also provide requirements for Class I and Class II nuclear facilities, uranium mines and mills, and the use of nuclear substances. The Canadian Nuclear Safety Commission By-laws and the *Canadian Nuclear Safety Commission Rules of Procedure* define the management and conduct of the Commission's affairs.

More information about all regulations under the NSCA can be found on the List of regulations on the CNSC website.

3.3 Licences and certificates

3.3.1 Licences

Section 26 of the NSCA describes activities that no person shall conduct except in accordance with a licence. The NSCA gives the Commission the power to grant licences for these activities.

All applicable licence conditions are reflected in the respective licence, including those that require the licensee to ensure that qualified personnel carry out the licensed activities, and that adequate provision is made for the protection of the environment, the health and safety of persons, and the maintenance of Canada's domestic and international obligations.

For more information on licensing, see section 5.3 of this document.

3.3.2 Certificates

The CNSC also issues certificates for people to carry out prescribed duties and for the use of prescribed equipment, and for the packaging and transport of nuclear substances. In each case, the certificate sets out applicable regulatory requirements. See section 5.4 for more information on certification.

3.4 CNSC regulatory documents and industry standards

In addition to the NSCA and the regulations made under it, the CNSC has developed regulatory documents, which are a key part of its regulatory framework for nuclear activities in Canada. They provide additional clarity to licensees and applicants by explaining how to meet the requirements set out in the NSCA and the regulations made under it. Regulatory documents are organized into three key categories: regulated facilities and activities, safety and control areas, and other areas of regulatory engagement.

The CNSC maintains an efficient and streamlined regulatory framework by making appropriate use of industry standards. These include, but are not limited to, standards created by independent, third-party standard-setting organizations such as the CSA Group, the American Society of Mechanical Engineers, the International Commission on Radiological Protection and the Institute of Electrical and Electronics Engineers. Industry or international standards may be referenced in CNSC regulatory documents.

More information about the CNSC's regulatory documents and CSA Group nuclear standards can be found on the CNSC's Regulatory documents Web page.

3.5 Safety and control areas

Safety and control areas (SCAs) are the technical topics that CNSC staff use to assess, review, verify and report on regulatory requirements and performance across all regulated facilities and activities. By providing a common language and architecture, SCAs improve understanding and communication within the CNSC, as well as between the CNSC and licensees, the Commission and other stakeholders. The CNSC's 14 SCAs are organized in three functional areas: management, facility and equipment, and core control processes.

SCAs do not constrain the CNSC in its conduct of regulatory oversight activities. Additional topics may be added as needed to provide satisfactory assurance of compliance.

Appendix B provides a table that lists the SCAs and their respective specific areas.

3.6 Role of consultation in the regulatory framework

Consultation with the public, licensees and other stakeholders is an integral component of developing the CNSC's regulatory framework. Regulations and regulatory documents published by the CNSC are generally subject to a formal public consultation process. Meetings and workshops may be organized to engage stakeholders and solicit feedback on the development of regulatory policies, requirements and guidance, and on what regulatory instruments are appropriate.

When proposing changes to the regulatory framework, the CNSC uses a variety of means to actively seek input from licensees, the public, non-governmental organizations, all levels of government, and international stakeholders. All input gained from these activities is considered when the CNSC develops and maintains its regulatory instruments. The CNSC uses discussion papers to solicit early feedback from stakeholders about the development of new or amended regulations, and when it is considering new areas of oversight or exercising its existing regulatory authority in a new manner.

The CNSC communicates openly and transparently with stakeholders, while respecting Canada's access to information and privacy laws. It consults stakeholders when establishing priorities,

developing policies and planning programs and services. The CNSC also cooperates with other jurisdictions to increase efficiency and effectiveness; for example, entering into formal arrangements where appropriate.

4. Public and Aboriginal engagement

4.1 Commission proceedings

Commission proceedings include public hearings and public meetings. At public hearings, the Commission hears information pertaining to the making of licensing and certification decisions. Public meetings are used to brief the Commission about significant developments that affect the nuclear regulatory process, or to ask the Commission to make administrative decisions or deal with administrative issues.

Interested parties can be heard in the public hearing process. With respect to public meetings, interested parties are invited to observe, but do not usually participate. Hearings and meetings can also be viewed online as webcasts.

4.2 Dissemination of objective scientific, technical and regulatory information

As part of its mandate to disseminate objective scientific, technical, and regulatory information, the CNSC informs the public about the development, production, possession, transport and use of nuclear substances on an ongoing basis. This is accomplished through various means, including:

- regulatory documents, decisions, reports, and plans posted to the CNSC website
- public Commission hearings and meetings
- live webcasts during Commission hearings and meetings
- social media platforms (YouTube, Facebook, Twitter and LinkedIn) and online resources (available on the CNSC website) that provide technical and scientific information in plain language
- public information sessions
- public consultation on, and publication of, regulations and regulatory documents
- sessions across Canada, to familiarize people with the CNSC and its role, and how they can participate in CNSC regulatory processes

In addition, the CNSC encourages its experts to share their knowledge, and it publishes scientific and technical paper abstracts, as well as journal articles authored by CNSC staff on its website. Staff also attend national fairs and conferences that specifically target youth, municipalities, and the medical community. This ongoing dialogue is important for increasing public understanding and trust in the CNSC.s role of protecting Canadians, their health, and the environment.

4.3 Aboriginal consultation and engagement

The CNSC seeks opportunities to work with Indigenous Peoples to understand any concerns they may have about the nuclear sector, and to ensure the safe and effective regulation of nuclear energy and materials.

As an agent of the Crown, the CNSC is responsible for fulfilling its legal duty to consult, and where appropriate, accommodate Indigenous Peoples when its decisions may have an adverse

impact on potential or established Aboriginal and/or treaty rights pursuant to section 35 of the *Constitution Act, 1982*.

The CNSC's approach to Aboriginal consultation includes commitments to uphold the honour of the Crown through information sharing, relationship building and promoting reconciliation, as well as to meeting its common-law duty to consult. The CNSC supports a coordinated, whole-of-government approach to improve the efficiency and effectiveness of the consultation process.

The CNSC cannot delegate its obligation, but can assign procedural aspects of the consultation process to licensees. In many cases, licensees are best positioned to collect information and propose any appropriate additional measures. The information collected and measures proposed by licensees to avoid, mitigate or offset adverse impacts is used by the CNSC in meeting its obligations and in its efforts toward reconciliation.

For further information on the CNSC's approach to Indigenous consultation and engagement, see REGDOC-3.2.2, *Aboriginal Engagement* [3].

5. The CNSC's Regulatory Approach

As discussed earlier in this document, the CNSC regulates to prevent unreasonable risk to the environment, the health and safety of persons, and national security. To this end, the CNSC has established a licensing and compliance system to ensure that all persons who use or possess nuclear substances and radiation devices do so in accordance with a licence, and that regulated parties have safety and security provisions in place that ensure compliance with regulatory requirements.

This section addresses the major elements that comprise the CNSC's regulatory approach.

5.1 Regulatory philosophy

The CNSC's regulatory philosophy is based on the following:

- Licensees are directly responsible for managing regulated activities in a manner that protects health, safety, security and the environment, and that conforms with Canada's domestic and international obligations on the peaceful use of nuclear energy.
- The CNSC is accountable to Parliament and to Canadians for assuring that these responsibilities are properly discharged.

The CNSC therefore ensures that regulated parties are informed about requirements and provided with guidance on how to meet them, and then verifies that all regulatory requirements are and continue to be met.

5.2 Continuous improvement

The CNSC is committed to continuous improvement of both its internal operations and its regulation of the Canadian nuclear industry. The CNSC therefore requires licensees to strive to further reduce the risks associated with their licensed activities on an ongoing basis. It assesses how licensees manage risk during both normal operations and in response to potential accident conditions applying concepts such as the ALARA[3] principle and defence in depth (see section 4.3,). In its assessments, the CNSC considers how licensees continuously evaluate, manage, and further reduce uncertainties with respect to hazards and safety issues. This also includes assessing how licensees consider additional safety and mitigation options as techniques and technologies evolve.

5.3 Defence in depth

CNSC requirements necessitate the implementation of defence in depth (DiD) in the design, construction and operation of nuclear facilities or the undertaking of nuclear activities. With DiD, more than one layer of defence (i.e., protective measure) is in place for a given safety objective, so that the objective will still be achieved even if one of the protective measures fails.

To achieve this, multiple independent layers of defence must be put into place to the extent practicable, taking organizational, behavioural, and engineered safety and security elements into account, such that no potential human or mechanical failure relies exclusively on a single layer of defence.

DiD applies to a wide range of facilities and activities. Appendix A illustrates how the different levels are defined for nuclear power plants.

5.3.1 Emergency preparedness

With regard to emergency preparedness and response, the CNSC has multiple emergency-related roles that translate to reducing risk in the event of an emergency. The CNSC regulates licensees' onsite emergency plans at nuclear facilities, ensures that applicants provide support to and have arrangements in place with offsite authorities (such as municipal and provincial governments), and is also part of the whole-of-government approach to federal nuclear emergency planning.

In the unlikely event of a nuclear emergency, the CNSC's role is to monitor and evaluate the actions of any nuclear operators involved, provide technical advice and regulatory directives when required, and inform the government and the public of its assessment of the situation. The CNSC's emergency preparedness program ensures well-coordinated, suitable responses to emergencies by integrating with nuclear operators; municipal, provincial and federal government agencies; first responders; and international organizations. The program is regularly tested

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[3] A principle of radiation protection that holds that exposures to radiation are kept as low as reasonably achievable (ALARA) , social and economic factors taken into account. Section 4 of the *Radiation Protection Regulations* stipulates licensee requirements with respect to ALARA. A similar principle, best available technology and techniques economically achievable (BATEA), may also be applied to releases of hazardous substances.

through exercises that involve simulated incidents in coordination with licensees and government agencies.

5.4 Graded approach

The graded approach is a systematic method or process by which elements such as the level of analysis, the depth of documentation and the scope of actions necessary to comply with requirements are commensurate with:

- the relative risks to health, safety, security, the environment and the implementation of international obligations to which Canada has agreed
- the particular characteristics of a nuclear facility or licensed activity

The CNSC applies the graded approach to licensing and compliance activities.

This approach is driven primarily by assessment of the risk associated with the activities being regulated, and the performance history of the licensee.

The degree of oversight is also informed by:

- the complexity and potential harm posed by the licensed activity
- technical assessments of submissions
- relevant research
- information supplied by parties to Commission proceedings
- international activities that advance knowledge in nuclear and environmental safety
- cooperation with other regulatory bodies

When applying the risk-informed approach, the following principles are adhered to:

- the meeting of regulatory requirements
- the maintenance sufficient safety margins
- the maintenance of defence in depth

If a licensee cannot achieve the required level of safety, it will not be permitted in any case to continue conducting its licensed activities.

5.5 Protection of the environment

Environmental protection is a shared federal–provincial responsibility. The CNSC cooperates with other jurisdictions and departments and, where appropriate, enters into formal arrangements to protect the environment more effectively and to coordinate regulatory oversight.

The CNSC's environmental protection mandate includes design objectives and best practices to minimize or eliminate the release of nuclear or hazardous substances to the environment. Environmental protection measures are commensurate with the level of risk associated with the activity. The CNSC determines whether a licensee or applicant will make adequate provision to protect the environment against unreasonable risk, and verifies compliance with associated regulatory requirements.

For further information on environmental protection, see REGDOC-2.9.1, *Environmental Principles, Assessments and Protection Measures* [4].

5.6 Protection of the health and safety of persons

The CNSC sets dose limits that are within the protective health limits and establishes regulations that set requirements to prevent unreasonable risk to the health and safety of persons. These limits are described in the *Radiation Protection Regulations* and are consistent with the recommendations of the International Commission on Radiological Protection (ICRP).

The Radiation Protection Regulations also require every licensee to implement a radiation protection program that takes into consideration the ALARA principle.

In addition to radiological hazards, regulating to prevent unreasonable risk to the health and safety of persons addresses conventional health and safety hazards.

5.7 Protection of national security

To prevent risk to national security, the CNSC works closely with nuclear facility operators, law enforcement and intelligence agencies, international organizations, and other governmental departments to ensure that nuclear substances and facilities are adequately protected. Nuclear security in Canada is aided by the *Nuclear Security Regulations* under the *Nuclear Safety and Control Act*. These regulations set out detailed security requirements for licensed nuclear facilities and other regulated activities.

5.8 International obligations

The CNSC participates in international fora to provide global nuclear leadership and to benefit from international experience and best practices. It also participates in undertakings implemented by the International Atomic Energy Agency (IAEA) (for example, IAEA peer reviews), the ICRP and other international organizations, as well as in activities under certain treaties such as the *Convention on Nuclear Safety* [5].

These international activities help inform the CNSC's decision-making processes to:

- understand and compare various ways of evaluating and mitigating risks
- share research and operational experience

5.9 Nuclear non-proliferation

The CNSC is responsible for implementing Canada's nuclear non-proliferation commitments and government policy:

- to assure Canadians and the international community that Canada's nuclear exports do not contribute to the development of nuclear weapons or other nuclear explosive devices
- to promote a more effective and comprehensive international nuclear non-proliferation regime

The international *Treaty on the Non-Proliferation of Nuclear Weapons* [6] (NPT) is the cornerstone of Canada's efforts to promote its objectives of international disarmament, non-proliferation, and the peaceful use of nuclear energy. NPT commitments to which Canada has agreed include:

- to not receive, manufacture, or acquire nuclear weapons or other nuclear explosive devices
- to accept IAEA safeguards on all nuclear material for peaceful use in Canada
- to ensure that Canada's nuclear material exports are subject to IAEA oversight

The CNSC implements these commitments through the NSCA and corresponding regulations, including the *Nuclear Non-proliferation Import and Export Control Regulations*.

5.10 Safeguards

The term "safeguards" refers to the measures taken by the IAEA, in accordance with the NPT, to verify that nuclear material is not diverted from peaceful uses to the development of nuclear weapons. The safeguards agreements between the Government of Canada and the IAEA give the IAEA the right and obligation to monitor Canada's nuclear-related activities, and to verify nuclear material inventories and flows in Canada.

Through its regulatory oversight, the CNSC ensures that all applicable licensees have safeguards programs in place to allow for:

- monitoring and reporting on nuclear material and activities
- providing IAEA safeguards inspectors with access to areas where nuclear material is stored, and to certain specified nuclear-related manufacturing and research activities
- providing operational and design information for nuclear facilities to the IAEA

Where required by the safeguards agreements, the CNSC compiles licensee information and submits it to the IAEA on behalf of the Government of Canada. The CNSC also cooperates with the IAEA in developing new safeguards approaches for Canadian facilities, and contributes to efforts to strengthen IAEA safeguards internationally.

6. Licensing and Certification

The Commission makes independent, objective and risk-informed decisions, taking into consideration all of the information provided by applicants, stakeholders, Indigenous peoples, and staff. CNSC staff make recommendations to the Commission based on thorough assessment of factual evidence. The Commission recognizes the role of professional judgment, particularly in areas where no objective standards exist.

6.1 Licensing

The licensing process consists of submission of a licence application, an assessment of the application by CNSC staff, and a decision by the Commission. The CNSC considers both the complexity of the nuclear activity and the regulatory approach determined to be the most appropriate, given the relative risks.

6.1.1 Licensing basis

The licensing basis sets the boundary conditions for a regulated activity, and establishes the basis for the CNSC's compliance program for that regulated activity.

All licensees are required to conduct their activities in accordance with the licensing basis, which is defined as a set of requirements and documents for a regulated activity comprising the following:

1. The regulatory requirements set out in the applicable laws and regulations

2. The conditions and safety and control measures described in the licence, and the documents directly referenced in that licence

3. The safety and control measures described in the licence application and the documents needed to support that licence application

Documents needed to support the licence application are those documents that demonstrate that the applicant is qualified to carry out the licensed activity, and that appropriate provisions are in place to protect worker and public health and safety, to protect the environment, and to maintain national security and measures required to implement international obligations to which Canada has agreed. Examples are detailed documents supporting the design, safety analyses and all aspects of operation to which the licensee makes reference, documents describing conduct of operations, and documents describing conduct of maintenance.

6.1.2 Licence conditions handbook

The CNSC's licensing regime includes the licence conditions handbook (LCH), which is a companion piece to interpret a licence. The general purpose of the LCH is, for each licence condition, to clarify the regulatory requirements and other relevant parts of the licensing basis.

The LCH, which should be read in conjunction with the licence, provides compliance verification criteria that the licensee must follow to comply with licence conditions, operational limits and information on delegation of authority and applicable versions of documents referenced in the licence. The LCH also provides non-mandatory recommendations and guidance on how to comply with licence conditions and criteria.

6.2 Certification

Certification applies to persons carrying out prescribed duties and the use of prescribed equipment, and to the packaging and transport of nuclear substances.

6.2.1 Certification of persons

Positions identified in regulations or a licence must hold a CNSC certification. The purpose of personnel certification is to regulate personnel who are assigned to positions that have a direct impact on the safe operation of a facility, or on the health and safety of workers, the public or the environment.

The CNSC's regulatory framework defines CNSC requirements and expectations for certification processes, including the qualifications, training, and examinations necessary to become certified, and the work experience, training and testing necessary to maintain a certification.

6.2.2 Certification of prescribed equipment

Certification of equipment is an attestation from the CNSC that prescribed equipment[4] is safe for use by qualified personnel. No prescribed equipment – barring exemptions such as smoke detectors and other equipment with a very small amount of a nuclear substance – can be used in Canada unless it is certified model or used in accordance with a CNSC licence.

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[4]Prescribed equipment is defined as the equipment prescribed by section 20 of the *General Nuclear Safety and Control Regulations*.

Note 1: Section 20 of the *General Nuclear Safety and Control Regulations* states that each of the following items is prescribed equipment for the purposes of the *Nuclear Safety and Control Act* (NSCA):

(a) a package, special form radioactive material, low dispersible radioactive material, fissile-excepted radioactive material, radioactive material that has a basic radionuclide value that is not listed in the IAEA Regulations and an instrument or article that has an alternative activity limit for an exempt consignment, as those terms are defined in subsection 1(1) of the *Packaging and Transport of Nuclear Substances Regulations, 2015*;
(b) a radiation device and a sealed source, as defined in section 1 of the *Nuclear Substances and Radiation Devices Regulations*;
(c) Class II prescribed equipment, as defined in section 1 of the *Class II Nuclear Facilities and Prescribed Equipment Regulations*; and
(d) equipment that is capable of being used in the design, production, operation or maintenance of a nuclear weapon or nuclear explosive device.

Note 2: All controlled nuclear equipment is prescribed equipment for the purposes of the NSCA, with respect to the import and export of that equipment.

6.2.3 Certification of transport packaging

The CNSC issues licences and certificates for packaging and transport of nuclear substances, as stipulated in the *Packaging and Transport of Nuclear Substances Regulations, 2015* (PTNSR 2015). These regulations are based on the IAEA's *Regulations for the Safe Transport of Radioactive Material* (2012 Edition) (IAEA Regulations).

The CNSC's REGDOC-2.14.1, *Information Incorporated by Reference in Canada's Packaging and Transport of Nuclear Substances Regulations, 2015*,[7] helps the regulated community comply with the PTNSR 2015. REGDOC-2.14.1 links provisions in the regulations to relevant content in the IAEA Regulations, the *Nuclear Safety and Control Act* (NSCA), other CNSC regulations, and other related information.

The CNSC regulates all aspects of the packaging and transport of nuclear substances, including the design, production, use, inspection, maintenance and repair of packages. In addition, the PTNSR 2015 require certain types of package design to be certified by the CNSC before being used in Canada. The PTNSR 2015 also provide for the certification of special form radioactive material confirming that the sealed source containing the radioactive material is designed to be strong enough to maintain leak tightness under the conditions of use and wear for which the sealed source was designed.

6.3 Pre-licensing and pre-certification engagement

The CNSC provides applicants with the option to engage in pre-licensing or pre-certification activities to facilitate discussion between stakeholders, the CNSC and any other relevant government bodies prior to submitting a licence or certificate application. These interactions may facilitate understanding of regulatory processes and requirements, while also allowing for early identification and resolution of potential regulatory or technical issues. Pre-licensing and pre-certification activities can only inform a licensing or certification process; they do not result in issuance of a licence or certificate under the NSCA, and in no way fetter the Commission's decision-making authority.

Pre-licensing engagement can vary in complexity from process-related questions to technical assessments that provide feedback to a potential applicant. An example of a pre-licensing technical assessment is a CNSC review of a proposed facility design to identify problems and means for their resolution.

Pre-licensing and pre-certification activities may also allow potential regulatory or technical issues to be identified early on, and improve an applicant's understanding of the CNSC's regulatory processes and requirements.

6.4 Application assessment by CNSC staff

When the CNSC receives a licence application, staff evaluate it to determine if the proposed safety and control measures described in the application, and the documents needed to support the application, are adequate meet applicable requirements.

Documents needed to support the licence application are those documents that demonstrate that the applicant is qualified to carry out the licensed activity, and that appropriate provisions will be made to protect worker and public health and safety, to protect the environment, and to maintain national security and measures required to implement international obligations to which Canada has agreed. Examples include detailed documents supporting the design, safety analyses and all

aspects of operation to which the applicant makes reference; documents describing conduct of operations; and documents describing conduct of maintenance.

Regulatory documents and industry standards may be referenced in the information supplied by an applicant in support of its licence application, and are used by CNSC staff to evaluate the application. These regulatory documents and standards become part of the licensing basis when referenced in the licence application or its supporting documentation, or when directly referenced in a licence.

Information submitted in support of an application must demonstrate that proposed safety and control measures will meet or exceed CNSC expectations. All submissions are expected to be supported by appropriate analytical, experimental or other suitable evidence. When deciding whether to renew an existing licence, the Commission also considers past performance by verifying compliance history.

Technical assessments are conducted to support licensing, compliance, regulatory decision making and development of regulatory positions. CNSC staff perform these assessments based on the best available science (such as technical knowledge and analytical methods), taking operating experience into consideration. Technical assessments determine whether submitted documents and supporting evidence presented to the CNSC by any stakeholder have a sound technical basis, measured against the CNSC regulatory framework. These assessments address the completeness (coverage and adequacy), comprehensiveness (depth), and the validity of the rationale and technical justification provided in submissions, and are also used to verify licensee compliance with regulatory requirements.

If CNSC staff conclude that an application is not complete or satisfactory, the applicant will be asked to submit additional information. Normally, applications do not proceed to a decision until staff are satisfied with the application.

6.5 Licensing and certification decisions

Licensing decisions include the issuance, refusal, amendment, renewal, suspension, revocation, replacement or transfer of a licence. Certification and decertification are determined by way of certification decisions. The CNSC's independence and transparency in decision making are supported by fair, open, transparent and predictable regulatory processes. Commission hearings provide stakeholders with the opportunity to be heard, and the Commission takes stakeholder input into consideration in its decision-making processes. In addition, the Commission recognizes the role of professional judgment, particularly in areas where no objective standards exist.

The Commission is the overall decision-making authority for all licensing matters. For decisions related to some low-risk facilities or activities, the Commission delegates its decision-making authority to certain CNSC staff members called designated officers (DOs). For more risk-significant facilities and activities, decisions are made by the Commission.

CNSC staff make recommendations to the Commission, and the Commission considers those recommendations along with input from external stakeholders (including the applicant or licensee) in its decision making. The Commission or the DO issues the licence or certificate, adding conditions as appropriate.

If the Commission deems it to be in the public interest to do so, then licensing decisions involve public hearings before the Commission. Commission proceedings are open to the public and are webcast live on the CNSC website.

7. Compliance

Once a license is issued, CNSC staff continue oversight through a compliance program. Compliance is defined as conformity by regulated persons or organizations with the requirements of the *Nuclear Safety and Control Act* (NSCA), the regulations made under the NSCA, licences, certificates, decisions, and orders made by the CNSC.

The licensee bears the primary responsibility for safety at all times, including compliance with regulatory requirements. The CNSC undertakes necessary and reasonable measures to ensure compliance. These measures include influencing compliance awareness, verification and enforcement (see sections 6.2 to 6.4 for more information on compliance verification and enforcement).

The CNSC holds information sessions and communicates with licensees regularly, in order to increase licensees' awareness of their responsibilities and to promote compliance.

7.1 Planning of compliance verification activities

The CNSC's compliance planning process ensures that compliance activities are carried out in a systematic and risk-informed manner. Annual compliance work plans outline the scope, scheduling, resourcing and timeframe for the activities to be undertaken for the next compliance cycle for a particular licence or class of licence.

The CNSC has developed a set of compliance verification activities that are based on the ongoing review of previous compliance findings and operational information. Once approved by the CNSC, any changes proposed by the licensee during the course of the given year are evaluated and documented using a risk-informed approach. Progress reviews are conducted periodically to monitor execution of the plan.

7.2 Compliance verification

The CNSC inspects and reviews operational activities and documentation to verify licensee compliance with requirements. The frequency, scope, type and depth of these inspections and reviews are risk-informed. Where there may be overlap in regulatory oversight with other regulatory bodies, the CNSC coordinates its verification activities to optimize efficiency and reduce administrative burden on licensees.

To evaluate licensee compliance, the CNSC conducts both field verification activities and desktop reviews.

Field verification activities include inspections and other surveillance and monitoring activities. Inspection is the process by which the CNSC inspectors gather data from the site of a licensed activity and analyze the data, for the purpose of confirming that workers, activities, facilities, and equipment are in compliance with the given licensing basis.

CNSC inspections are led by designated inspectors and are planned, controlled, coordinated, consistent and transparent (open to formal scrutiny). Conducted in alignment with the SCAs, the objectives of inspections are defined and communicated to licensees. Licensees are also made aware of inspection criteria, and of the standards of performance and methodologies being used.

Desktop reviews generally entail consideration of documents and reports, such as quarterly technical reports, annual compliance reports, special reports, and documentation related to design, safety analysis, programs and procedures. Licensees are required to provide information to the

CNSC through baseline reporting (scheduled) and event reporting. They are also expected to notify the CNSC of changes to operating processes, procedures or programs, or to submit written requests of such changes. In all cases, the CNSC assesses this information to ensure that operations remain within the licensing basis.

Where a deficiency or deviation is either self-identified by the licensee or detected by CNSC staff, the regulated party is expected to address or correct the situation promptly. If necessary, the CNSC may also take enforcement action to compel compliance with regulatory requirements.

7.3 Enforcement

The purpose of enforcement is to compel licensees or regulated persons back into compliance where non-compliance is detected. The CNSC does not take enforcement action to punish, but rather to encourage compliance, to maintain continued safety, and to deter further non-compliance.

The CNSC uses a graded approach to enforcement. Regulated parties typically identify and self-correct non-compliances on an ongoing basis; however, where enforcement is indicated, the appropriate enforcement action for the given situation is determined, taking into account such considerations as:

- the risk significance of the non-compliance with respect to health, safety, security, the environment and international obligations
- the circumstances that lead to the non-compliance (including acts of willfulness)
- the compliance history of the regulated party
- operational and legal constraints (for example, the *Directive to the Canadian Nuclear Safety Commission Regarding the Health of Canadians*)
- industry-specific considerations

Enforcement actions include informal discussion, orders, administrative monetary penalties and legal prosecution. Any enforcement action can be used independently or in combination with others, resulting in a wide range of options for the CNSC.

7.4 Compliance reporting

CNSC staff report to the Commission, the public, licensees, the Government of Canada, the International Atomic Energy Agency, and other interested parties on the results of compliance verification and enforcement activities. Compliance reports document the safety performance of regulated activities, and are based on the CNSC's independent evaluation of compliance and licensee performance.

Appendix A: Levels of Defence in Depth for Nuclear Power Plants

Defence in depth is a principle implemented primarily through a combination of multiple consecutive and independent levels of protection. For nuclear power plants, defence in depth consists of different levels of equipment and procedures to maintain the effectiveness of physical barriers placed between radioactive materials and workers, the public, or the environment. Table A shows an example of the objectives and implementation of each level in a defence-in-depth regime for a nuclear power plant.

Table A: Objectives and implementation of defence in depth for nuclear power plants

Level	Objective	Implementation
1	Normal operation: To prevent deviations from normal operation, and to prevent failures of structures, systems and components (SSCs) important to safety.	• Conservative design • High-quality materials, manufacturing and construction (e.g. appropriate design codes and materials, design procedures, equipment qualification, control of component fabrication and plant construction, operational experience) • A suitable site was chosen for the plant with consideration of all external hazards (e.g. earthquakes, aircraft crashes, blast waves, fire, flooding) in the design • Qualification of personnel and training to increase competence • Strong safety culture • Operation and maintenance of SSC in accordance with the safety case
2	Operational occurrences: To detect and intercept deviations from normal operation, to prevent AOOs from escalating to accident conditions and to return the plant to a state of normal operation.	• Inherent and engineered design features to minimize or exclude uncontrolled transients to the extent possible • Monitoring systems to identify deviations from normal operation • Operator training to respond to reactor transients
3	Design basis accidents: To minimize the consequences of accidents and prevent escalation to beyond design basis accidents.	• Inherent safety features • Fail-safe design • Engineered design features, procedures that minimize design basis accident (DBA) consequences • Redundancy, diversity, segregation, physical separation, safety system train/channel independence, single-point failure protection • Instrumentation suitable for accident conditions • Operator training for postulated accident response

4	Beyond design basis accidents: To ensure that radioactive releases caused by beyond design basis accidents, including severe accidents, are kept as low as practicable.	• Beyond design basis accidents guidance to manage accidents and mitigate their consequences as far as practicable • Robust containment design with features to address containment challenges (e.g. hydrogen combustion, overpressure protection, core concrete interactions, molten core spreading and cooling) • Complementary design features to prevent accident progression and to mitigate the consequences • Features to mitigate radiological releases (e.g. filtered vents)
5	Mitigation of radiological consequences: To mitigate the radiological consequences of potential releases of radioactive materials that may result from accident conditions.	• Emergency support facilities • Onsite and offsite emergency response plans and provisions • Plant staff training on emergency preparedness and response

Source: *Implementation of Defence in Depth at Nuclear Power Plants: Lessons Learnt from the Fukushima Daiichi Accident*, NEA No. 7248, 2016 [8].

Appendix B: Safety and Control Area Framework

The CNSC's regulatory requirements and expectations for the safety performance of programs are organized into a framework made up of 3 functional areas and 14 safety and control areas (SCAs), which are subdivided into specific areas. Table B outlines each functional area and their respective SCAs and specific areas.

Table B: Key elements of the CNSC's Safety and Control Area Framework

Functional area	Safety and control area	Specific area
Management	1. Management system	Management system
		Organization
		Performance assessment, improvement and management review
		Operating experience (OPEX)
		Change management
		Safety culture
		Configuration management
		Records management
		Management of contractors
		Business continuity
	2. Human performance management	Human performance program
		Personnel training
		Personnel certification
		Initial certification examinations and requalification tests
		Work organization and job design
		Fitness for duty
	3. Operating performance	Conduct of licensed activities
		Procedures
		Reporting and trending
		Outage management performance
		Safe operating envelope
		Severe accident management and recovery
		Accident management and recovery

Functional area	Safety and control area	Specific area
Facility and equipment	4. Safety analysis	Deterministic safety analysis
		Hazard analysis
		Probabilistic safety assessment
		Criticality safety
		Severe accident analysis
		Management of safety issues (including R&D programs)
	5. Physical design	Design governance
		Site characterization
		Facility design
		Structure design
		System design
		Component design
	6. Fitness for service	Equipment fitness for service / equipment performance
		Maintenance
		Structural integrity
		Aging management
		Chemistry control
		Periodic inspection and testing
Core control processes	7. Radiation protection	Application of ALARA
		Worker dose control
		Radiation protection program performance
		Radiological hazard control
		Estimated dose to public
	8. Conventional health and safety	Performance
		Practices
		Awareness
	9. Environmental protection	Effluent and emissions control (releases)
		Environmental management system (EMS)
		Assessment and monitoring

Functional area	Safety and control area	Specific area
		Protection of the public
		Environmental risk assessment
	10. Emergency management and fire protection	Conventional emergency preparedness and response
		Nuclear emergency preparedness and response
		Fire emergency preparedness and response
	11. Waste management	Waste characterization
		Waste minimization
		Waste management practices
		Decommissioning plans
	12. Security	Facilities and equipment
		Response arrangements
		Security practices
		Drills and exercises
	13. Safeguards and non-proliferation	Nuclear material accountancy and control
		Access and assistance to the IAEA
		Operational and design information
		Safeguards equipment, containment and surveillance
		Import and export
	14. Packaging and transport	Package design and maintenance
		Packaging and transport
		Registration for use

Glossary

For definitions of terms used in this document, see REGDOC-3.6, *Glossary of CNSC Terminology*.

REGDOC-3.6 includes terms and definitions used in the *Nuclear Safety and Control Act* and the regulations made under it, as well as in CNSC regulatory documents and other publications. REGDOC-3.6 is provided for reference and information.

References

1. International Atomic Energy Agency (IAEA), IAEA Information Circular 164 *Agreement Between the Government of Canada and the IAEA for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons*, Vienna, 1972

2. IAEA, IAEA Information Circular 164 Add.1 Protocol Additional to the Agreement between Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons, Vienna, 2000

3. Canadian Nuclear Safety Commission (CNSC), REGDOC-3.2.2, *Aboriginal Engagement*, Ottawa, Canada, 2016

4. CNSC, REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures*, version 1.1, Ottawa, Canada, 2017

5. *Convention of Nuclear Safety & Security* (http://www-ns.iaea.org/conventions/nuclear-safety.asp)

6. *Treaty on the Non-Proliferation of Nuclear Weapons* (http://www.un.org/en/conf/npt/2005/npttreaty.html)

7. CNSC, REGDOC-2.14.1, *Information Incoporated by Reference in Canada's Packaging and Transport of Nuclear Substances Regulations*, Ottawa, Canada, 2015

8. Nuclear Energy Agency (NEA), *Implementation of Defence in Depth at Nuclear Power Plants: Lessons Learnt from the Fukushima Daiichi Accident*, NEA No. 7248, 2016

Additional Information

- International Atomic Energy Agency, IAEA Safety Standards Series No. SF-1, *Fundamental Safety Principles: Safety Fundamentals*, 2006.
- For a list of all legislation relevant to the CNSC, visit the CNSC's List of regulations Web page.

CNSC Regulatory Document Series

Facilities and activities within the nuclear sector in Canada are regulated by the Canadian Nuclear Safety Commission (CNSC). In addition to the *Nuclear Safety and Control Act* and associated regulations, these facilities and activities may also be required to comply with other regulatory instruments such as regulatory documents or standards.

Effective April 2013, the CNSC's catalogue of existing and planned regulatory documents has been organized under three key categories and twenty-six series, as set out below. Regulatory documents produced by the CNSC fall under one of the following series:

1.0 Regulated facilities and activities

Series
- 1.1 Reactor facilities
- 1.2 Class IB facilities
- 1.3 Uranium mines and mills
- 1.4 Class II facilities
- 1.5 Certification of prescribed equipment
- 1.6 Nuclear substances and radiation devices

2.0 Safety and control areas

Series
- 2.1 Management system
- 2.2 Human performance management
- 2.3 Operating performance
- 2.4 Safety analysis
- 2.5 Physical design
- 2.6 Fitness for service
- 2.7 Radiation protection
- 2.8 Conventional health and safety
- 2.9 Environmental protection
- 2.10 Emergency management and fire protection
- 2.11 Waste management
- 2.12 Security
- 2.13 Safeguards and non-proliferation
- 2.14 Packaging and transport

3.0 Other regulatory areas

Series
- 3.1 Reporting requirements
- 3.2 Public and Aboriginal engagement
- 3.3 Financial guarantees
- 3.4 Commission proceedings
- 3.5 CNSC processes and practices
- 3.6 Glossary of CNSC terminology

Note: The regulatory document series may be adjusted periodically by the CNSC. Each regulatory document series listed above may contain multiple regulatory documents. For the latest list of regulatory documents, visit the CNSC's website.